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## SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

The ATAC PAK Albumin Reagent Kit is intended for the quantitative determination of albumin in serum and plasma. Albumin results are used for the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. The ATAC PAK Albumin Reagent determines albumin by the selective binding of bromocresol green. The resulting increase in absorbance at 630 nm is proportional to the albumin concentration in the sample.

The ATAC PAK Albumin Reagent Kit is substantially equivalent to the Roche Albumin Reagent Kit, product no. 1970569, which is marketed by Roche Diagnostics of Indianapolis, IN. The effectiveness of ATAC PAK Albumin Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of albumin using the ATAC PAK Albumin Reagent is linear from 0.1 to 8 g/dL, as shown by the recovery of linearity standards that span the usable range. Regression statistics compare standard recoveries to standard values. These statistics are shown below.

$$(\text{ATAC Recoveries}) = 0.04 \text{ g/dL} + 0.902 \times (\text{Reference Value}), \quad r = 0.999, \quad s_{y,x} = 0.11 \text{ g/dL}, \quad n = 33$$

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.


Precision of Albumin Recoveries in g/dL						
Sample	n	mean	Within Run		Total	
			ISD	%CV	ISD	%CV
Serum 1	60	2.5	0.06	2.5%	0.08	3.3%
Serum 2	60	3.9	0.09	2.3%	0.11	2.8%
Serum 3	60	5.3	0.09	1.6%	0.12	2.3%

Mixed serum and plasma specimens, collected from adult patients, were assayed for albumin using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

$$\text{ATAC 8000} = 0.5 \text{ g/dL} + 0.867 \times \text{Competitive Reagent}$$
$$s_{y,x} = 0.11 \text{ g/dL} \quad n = 119 \quad \text{range} = 1.9 - 5.4 \text{ g/dL}$$

The detection limit of 0.1 g/dL is documented through the repetitive assay of a diluted serum pool. The observed standard deviation of a 30 replicate within run precision study was 0.018 g/dL. Consequently, the detection limit is reported as the round-off error of the assay.

The 14 day onboard reagent stability and 7 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, the total imprecision of albumin recoveries over the test periods are less than 0.15 g/dL or 3%.

  
Wynn Stocking  
Manager of Regulatory Affairs  
Elan, Brea California



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAR 07 2003

Mr. Wynn Stocking  
Manager, Regulatory Affairs  
Elan Diagnostics  
1075 W. Lambert Road – Building D  
Brea, CA 92821

Re: k030006  
Trade/Device Name: ATAC PAK Albumin Reagent  
Regulation Number: 21 CFR 862.1035  
Regulation Name: Albumin test system  
Regulatory Class: Class II  
Product Code: CIX  
Dated: December 31, 2002  
Received: January 2, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

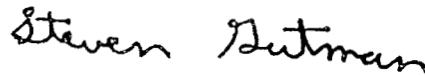
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

K030006

Device Name:

ATAC PAK Albumin Reagent

Indications for Use:

The ATAC PAK Albumin Reagent Kit is intended for use with the ATAC Calibrator and the ATAC 8000 Random Access Chemistry System as a system for the quantitative determination of albumin in serum and plasma. Albumin results are used for the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K030006

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)